

REMARKS/ARGUMENTS

Applicant acknowledges and thanks Examiner Gupta for the personal interview conducted in this application on March 18, 2008. During the interview, the undersigned indicated that a Preliminary Amendment would be submitted which further focused certain claims of the application, and those amendments are provided herein. Applicant was also requested to eliminate the use of trademarks in the claims, and this has been done in this amendment by replacing the terms Pluronic F68, Pluronic F77, Pluronic F87 and Pluronic F88 with their non-trademark designations poloxamer 188, poloxamer 217, poloxamer 237 and poloxamer 238, respectively.

The present application previously included claims 46-188, and was the subject of both a restriction requirement and an election of species. Claims 90-188 were previously restricted out of the application, and elected claims 46-89 have been examined, based on the species Pluronic F68 as the surfactant. Claims 72-74, directed to liquid pharmaceutical compositions including both FSH and LH, have been indicated to be allowable. Claims 46-71 and 75-89 have been rejected under §103.

In the Amendment submitted on September 19, 2007, the rejection of claims 46-71 and 75-89 under §103 was addressed. The rejected claims 65-71 and 81 were cancelled, as well as the non-elected claims 90-188. Claims 75-80, 82-86, and 88-89 were amended to depend from allowed claim 72, and claim 87 therefore now depends indirectly on claim 72, and these claims are therefore submitted to be allowable. New claims 189-197 were added which also depend directly or indirectly from claim 72, and those claims were therefore submitted to be allowable on that basis.

The other claims remaining in the case are claims 46-64 and 198-211, which are directed to pharmaceutical compositions including FSH, but not requiring luteinising hormone (which is included in the other claims). By this Preliminary Amendment, these FSH claims have been amended to provide two parallel sets of claims – one including m-cresol (claims 46-53 and 56-64), and the other including phenol (claims 198-211). Accordingly, claim 46 has been amended to reference m-cresol, claims 54 and 55 have been cancelled, and the dependencies of claims 56 and 61 have been changed to claim 46. As the claims therefore represent only a rearrangement of prior claim limitations, it is evident that the amended and new claims are supported in the specification.

Applicant has previously responded to art rejections of certain of these claims, and does not repeat those responsive arguments herein. However, in view of the amendment of the FSH claims to include m-cresol and/or phenol, applicant does again provide comments previously made regarding claims of this scope.

Claims 46-64 and 198-211 cover FSH compositions which include m-cresol or phenol as bacteriostatic agents. As indicated in the specification, the use of Pluronic F68 (or F77, F87 or F88) solves a problem of precipitation which occurs with certain other surfactants. Specifically, these claimed surfactants “obtain a stable formulation that avoids the problem of precipitation in the presence of a bacteriostatic agent, such as m-cresol and phenol. Precipitation, resulting in the formation of turbid or milky solutions occurs when TWEEN 20 is used with m-cresol or phenol.” Page 12, lines 28-35. As stated in Example 1:

“From visual examination of the formulations, it was determined that TWEEN 20 cannot be used with m-cresol and phenol because FSH formulations containing TWEEN 20 and m-cresol or TWEEN 20 and phenol presented a white opalescent suspension. In contrast, FSH formulations containing Pluronic F68 did not exhibit this problem with m-cresol and phenol. The use of Pluronic F68 permits the use of phenol and m-cresol.”

Applicant submits that this is an unobvious advantage for the formulations including m-cresol or phenol, and that those claims are therefore patentable over the cited art for this additional reason.

Reconsideration of the above-identified patent application, as amended and in view of the foregoing remarks, is respectfully requested. An action on the merits and allowance of the claims is solicited. If the Examiner believes that it would expedite examination of this case, the Examiner is requested to contact the undersigned directly.

Respectfully submitted,

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